**********DRAFT**********

DRAFT REGULATIONS
for
The Environmental Laboratory Accreditation Program (ELAP)

Development and posting of the draft ELAP regulations

In February 2004, a workgroup consisting of representatives from the Environmental Laboratory Technical Advisory Committee, the broader commercial laboratory community, the Department of Health Services Environmental Accreditation Program (ELAP), and other State programs began meeting to draft a revision of Chapter 19 in Title 22, which governs the certification of environmental laboratories.

The following draft reflects the workgroup's efforts during six months of almost weekly meetings. Please note the following:

- The draft presumes that changes in the statutes supporting the ELAP program will be made in 2005, to allow the program the flexibility to stay current with new methodology and expanding regulatory requirements for accredited laboratories.
- The first 20 pages are the existing regulations; these are "struck" since they would be repealed and replaced by the proposed regulations on pages 21-37.

The Department is posting this draft now to obtain "unofficial" input from stakeholders that have not yet been involved in the development process. "Unofficial" means that the Department is not required under law to respond (although we may anyway) and that you will have an "official" opportunity at a later date.

The workgroup will meet on November 2nd to review any submitted comments to consider revisions. Subsequently, the draft will be incorporated into a regulation package and submitted to the Office of Regulations to begin the adoption process, with an optimistic effective date in early spring 2006.

Please submit any comments you have to amilea@dhs.ca.gov
by October 25, 2004.

Thank you for your interest in these regulations.

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TITLE 22. Social Security
Division 4. Environmental Health
Chapter 19. Certification of Environmental Laboratories

~~**ARTICLE 1. DEFINITIONS.**~~

~~**§64801. Definitions.**~~

~~(a) "Alternate Test Procedure" means an analytical test method, or procedure that is different in technic from the method(s) cited in Section 64811(a), (b), or (c), but detects and quantifies to the same degree of precision, accuracy, and level of detection.~~

~~(b) "Auxiliary Laboratory Facility" means any stationary place which:~~

~~(1) is operated by the owner of a laboratory for the purpose of providing additional capacity, or to reduce or eliminate sample contamination; and~~

(2) performs analyses in one or more of the same Field(s) of Testing as the laboratory to which it is auxiliary; and

(3) is under the supervision of the same Laboratory Director as the laboratory to which it is auxiliary; and

(4) only receives samples from, and reports raw analytical data to, the laboratory to which it is auxiliary for its generation of the final report; and

(5) is located such that the transport of samples to the auxiliary laboratory does not affect the quality of the analytical results.

(c) "A Complete Application" means a verified application for certification containing all the information required in Section 64805(a) or (b), and utilizing ELAP form 001 (dated 1/1/93).

(d) "Contact Person" means an individual designated by the Laboratory Director to act as a contact between the laboratory and the Department for purposes of exchanging information between the Department and the laboratory.

(e) "Laboratory" shall have the same meaning as given in Health and Safety Code Section 1010(c)(2).

(f) "Laboratory Director" means the person who, for the laboratory and its auxiliary or mobile laboratories, if any, is in charge of all analytical and operational laboratory activities; supervises all personnel, including those designated as Principal Analysts; and is the person responsible for the quality of reported data.

(g) "Facility or Facilities" means fixed or portable building(s), which contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the Field(s) of Testing for which a laboratory is certified, and includes storage areas.

(h) "Mobile Laboratory" means a vehicle, vessel, aircraft, or trailer, which is certified under Field of Testing 23, and is operated by the same owner as a certified stationary laboratory, and which is designed and equipped for the purpose of transporting and using laboratory equipment to perform analyses in one of the Fields of Testing for which the stationary laboratory is certified.

(i) "Owner" means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

(j) "Owner's Agent" or "Agents of Owners" means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with these regulations or the statutes under which these regulations are adopted.

(k) "Principal Analyst" means a person who either supervises the activities of others in, or conducts, the analyses of environmental samples using sophisticated laboratory instruments. For these purposes, "sophisticated laboratory instruments" means: gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma spectrometers (ICP), direct current plasma spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), or high pressure liquid chromatographs (HPLC).

~~(l) "Stationary Laboratory" means a laboratory that is permanent and nonmovable and may include fixed-in-place vehicles.~~

~~(m) "Trade Secret" means any information that meets the definition in Section 6254.7(d) of the Government Code.~~

~~(n) "Trailer" means a vehicle designed for carrying persons or property on its own structure and for being drawn by a motor vehicle and so constructed that no part of its weight rests upon any other vehicle. This definition is the same as the definition given in Section 630, Vehicle Code.~~

~~(o) "Utility-Owned" means laboratories owned and operated by federal, state, city, or county agencies.~~

~~(p) "Vehicle" means a device by which any person or property may be propelled, moved, or drawn upon a highway, excepting a device moved exclusively by human power or used exclusively upon stationary rails or track. This definition is the same as the definition as given in Section 670, Vehicle Code.~~

~~(q) "Verified Application" means that the truth and accuracy of the information in the application has been attested to by the signature of a laboratory Owner.~~

~~(r) "Vessel" includes ships of all kinds, steamboats, steamships, canal boats, barges, sailing vessels, and every structure adapted to be navigated from place to place for the transportation of merchandise or persons. This definition is the same as given in Section 21, Harbors and Navigation Code.~~

NOTE: Authority cited: Sections 208. 1011 and 1012, Health and Safety Code. Reference: Sections 1010, 1014 and 1017, Health and Safety Code; Section 6254.7(d), Government Code; Sections 630 and 670, Vehicle Code; Section 21, Harbors and Navigation Code.

~~ARTICLE 2. CERTIFICATION AND AMENDMENT~~

~~§64803. Certification and Amendment.~~

~~(a) A laboratory and its auxiliary or mobile laboratories shall be certified for a 24 month period in the Subgroups within each Field of Testing applied for when all the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

~~(3) acceptable results for performance evaluation sample study sets have been received by the Department pursuant to Section 64809; and~~

~~(4) payment of the basic fee and per-Field-of-Testing fees published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) has been made to the Department.~~

~~(b) A laboratory desiring to add or remove one or more Subgroups within a Field(s) of Testing from its current certificate shall file a written request detailing the Field(s) of Testing or Subgroup(s) to be added or removed. Additions, which shall be effective for the remainder of the certification period, shall be made, and an amended certificate issued, when all of the following have occurred:~~

~~(1) a complete application has been filed with the Department pursuant to Section 64805; and~~

~~(2) a site visit pursuant to Section 64807 has occurred and a response to any cited deficiencies has been received and accepted by the Department; and~~

(3) acceptable results for performance evaluation samples have been received by the Department pursuant to Section 64809; and

(4) payment for a per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Sections 113 and 1017(a) for each Field of Testing to be added to the certificate has been made to the Department.

(c) Whenever there is an amendment to a certificate, the certificate number and the expiration date on the amended certificate shall be the same as the original certificate.

(d) Laboratories seeking an amendment to add one or more Subgroups within a Field(s) of Testing shall not perform analyses in the additional Field(s) of Testing, or Subgroup(s) of Field(s) of Testing, until approved by the Department as evidenced by the issuance of an amended certificate.

(e) Laboratories seeking removal of one or more Subgroups within a Field(s) of Testing shall not perform analyses in the Field of Testing, or Subgroup, after the date of its written request for removal.

(f) A laboratory desiring interim certification under authority of Health and Safety Code, Section 1015(d) shall file a written request for interim certification with its application. An interim certificate shall be issued after payment of the basic and per-Field-of-Testing fee published by the Department pursuant to Health and Safety Code, Section 113 and 1017(a) for each Field of Testing applied for, completion of the requirements of either Section 64807 or 64809, and after the Department has determined that the laboratory has submitted a complete application. In cases where reciprocity agreements exist, compliance with Section 64807 shall be based on a site visit report issued by the other government agency and conducted within 6 months prior to the request for interim certification.

(g) The Department's estimated schedule for processing a complete application for certification from the receipt of the complete application to the final decision regarding issuance or denial of a certificate is as follows:

(1) The median time is 6 months;
(2) The minimum time is 3 months;
(3) The maximum time is 12 months.

NOTE: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code; and Section 15376, Government Code. Reference: Section 15376, Government Code; and Sections 113, 1012, 1013, 1014 and 1015, Health and Safety Code.

§64806. Certification Fees.

(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal Environmental Laboratory Accreditation Program certification:

(1) A non-refundable base or administrative fee of $959 payable at the time of initial and renewal application for certification and annually thereafter, and

(2) An additional fee of $432 for each Field of Testing specified in Health and Safety Code Section 100860.1 which the laboratory has requested in its application, payable at the time of application for an initial, amended, or renewed ELAP certification, and annually thereafter.

(b) For a certificate issued between 01/01/02 and 12/31/02, the fee required at the time of the initial and renewal application shall be due and payable within the time period for which the certificate is valid and within 30 days notice by the Department.

NOTE: Authority cited: Sections 100830, 100835(a) and 100860.1, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

ARTICLE 4. SITE VISITS

§64807. Site Visits.

(a) Site visits shall be conducted by the Department to verify information contained in a laboratory's application for certification or when a laboratory requests the addition of one or more Subgroups within a Field of Testing. During the site visit, the Department shall verify the following:

(1) the laboratory uses only the analytical test methods identified in Section 64811 for each Subgroup within a Field of Testing for which the laboratory is seeking certification;

(2) the laboratory's instrumentation and equipment meet the requirements of Section 64813;

(3) the laboratory's quality assurance and quality control procedures meet the requirements of Section 64815; and

(4) the information contained in the application.

(b) Within 30 days of completion of a site visit, the Department shall notify a laboratory, in writing, of its deficiencies, if any, in complying with the requirements of (a)(1) through (a)(4) above. No laboratory shall be issued a certificate in any Subgroup within any Field of Testing applied for unless it has corrected all deficiencies noted, and has forwarded to the Department a statement, in writing, of all corrective actions taken. The statement of corrective actions shall be received by the Department within the time frame established in the Department's notice of deficiencies. If in a subsequent site visit the Department determines that the laboratory failed to take any of the corrective action(s) specified in the laboratory's statement, citation(s) as specified under the authority of Health and Safety Code, Section 1021, may be issued.

(c) A site visit shall be conducted within 6 months from the date of receipt by the Department of a laboratory's application. If a site visit is not conducted within this time period and the delay is not a result of Department error or procedure, certification shall be denied pursuant to Section 64803(a)(2).

NOTE: Authority cited: Sections 208, 1011 and 1012, Heath and Safety Code. Reference: Sections 1015, 1018 and 1021, Health and Safety Code.

ARTICLE 5. PERFORMANCE EVALUATION TESTING PROCESS

§64809. Performance Evaluation Testing.

(a) No laboratory shall be certified to perform analyses in any Subgroup of any Field(s) of Testing as identified in Section 64823 unless the laboratory has submitted results for the analysis of performance evaluation sample study set(s) (where performance evaluation sample study set(s) exist) in each Subgroup within each Field of Testing for which certification is requested, and the results for the testing of the study set are in agreement with the criteria established below:

(1) within the 99% confidence limit of the mean computed by the Department for the collection of results received for the performance evaluation sample set for the following Subgroups: detection of total coliform or fecal coliform organisms in wastewater by Multiple Tube Fermentation technics; detection of total coliform or fecal coliform organisms in wastewater by Membrane Filter technics; Heterotrophic Plate Count technics; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics; Fecal streptococci and Enterococci by Membrane Filter technics of Field of Testing 1; all Subgroups in Fields of Testing 6, 9, 10, 12, 13, 16, 17, 18, and 19;

(2) positive/negative, present/absent, above/below, or other similar discrete response when the only result possible from a test is a discrete response for the following Subgroups in Field of Testing 1: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by Membrane Filter technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms in drinking water by use of Clark's Presence/Absence medium; detection of both total coliforms and Escherichia coli (E. coli) organisms in drinking water by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside - 4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics;

(3) for all Subgroups in Field of Testing 8: within the 99% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set, or within the 95th percentile of a distribution of non-normal values. The choice determined by the Department through the application of standard tests that determine the normalcy of data;

(4) within the 95% confidence limit of the mean computed by the Department from the collection of results received for the performance evaluation sample set for the following Subgroups: alkalinity, calcium, chloride, corrosivity, hardness, magnesium, MBAS, sodium, sulfate, total filterable residue and conductivity, iron (colorimetric methods only), manganese (colorimetric methods only), and ortho phosphate in Field of Testing 2; asbestos in Field of Testing 3;

(5) within a given percentage of a known or true value for the following Subgroups: cyanide, fluoride, nitrate and nitrite in Field of Testing 2; all Subgroups in Field of Testing 3, except asbestos; all Subgroups in Fields of Testing 4, 5, 20, 21, and 22.

(b) Each performance evaluation sample study set shall state the method of evaluation that shall be utilized to score results for that performance evaluation sample study set, and which requirements identified in (a) above, or (c) below must be met by the laboratory.

(c) If a performance evaluation sample study set contains one or more analytes that may be analyzed by a single test method that the Department recognizes and certifies as a Subgroup of a Field of Testing, the results shall meet one of the following:

(1) when 6 or fewer analytes are in the performance evaluation sample study set, all analytes are within the stated acceptance limits; or

(2) when more than 6 analytes are in the performance evaluation sample study set, eighty-five point zero percent (85.0%) of the analytes are within the stated acceptance limits.

(d) If a laboratory fails to submit results for the analysis of performance evaluation sample study sets, which meet the above requirements, the laboratory may, within 30 days, request that it be given a second, successive attempt to submit such results. Failure of a laboratory to submit results for the analysis of performance evaluation sample study sets meeting the requirements of (a) or (c) within 6 months from the date of receipt by the Department of the laboratory's application for certification, or of its request for the addition of one or more Subgroups within a Field(s) of Testing shall result in the denial of the application or request.

(e) With the exception of Field of Testing 6, a certified laboratory shall, within 12 months from the date of certification, participate in at least one performance evaluation sample study set (where performance evaluation sample study set(s) exist) for each Subgroup within each Field of Testing as identified in Section 64823 for which certification is held. If the results from the study do not meet the requirements of (a) or (c), the laboratory shall be provided a second, successive attempt to submit such results. Irrespective of whether a second, successive attempt is provided, results meeting the requirements of (a) or (c) must be submitted by a certified laboratory to the Department at least 90 days prior to the

expiration of its certificate or the laboratory's certificate may be restricted under Health and Safety Code, Section 1015(c).

(f) Laboratories holding certification in any Subgroup within Field of Testing 6 shall participate in all available performance evaluation test samples provided through the Environmental Protection Agency's Environmental Monitoring and Support Laboratory, Las Vegas inter-comparison cross check and performance evaluation studies. The laboratory must successfully complete a minimum of two inter-comparison cross check studies and one performance evaluation study each annual period from the date of certification. Failure to do so may be used by the Department as grounds for restricting the laboratory's certificate under Health and Safety Code, Section 1015(c).

(g) Laboratories seeking or holding certification in any Subgroup within Field of Testing 11 are exempt from compliance with the requirements of Health and Safety Code, Section 1015(b)(1).

NOTE: Authority cited: Sections 208, 1011 and 1012, Heath and Safety Code. Reference: Sections 1015, 1017 and 1019, Health and Safety Code.

ARTICLE 6. REQUIRED TEST METHODS

§64811. Test Methods.

(a) Laboratories certified for any Subgroup within Fields of Testing 1 through 6, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 141 as amended July 17, 1992, 57 Federal Register 31776.

(b) Laboratories certified for any Subgroup within Fields of Testing 9 through 14, as identified in Section 64823, shall employ those methods found in Article 5, Section 66260.11, Title 22, California Code of Regulations.

(c) Laboratories certified for any Subgroup within Fields of Testing 8 or 16 through 19, as identified in Section 64823, shall employ those methods found in 40 Code of Federal Regulations Part 136, amended September 11, 1992, 57 Federal Register 41830, or methods stated in any permit issued by a California Regional Water Quality Control Board. If no method is stated in the permit and there is no method cited for the substance in Part 136, the laboratory is to seek approval for the use of the method from the Regional Board issuing the permit.

(d) Laboratories certified for any Subgroup within Fields of Testing 20, 21 or 22, as identified in Section 64823, shall develop and employ analytical confirmation procedures for the verification of pesticide identification and quantification.

(e) Laboratories certified in any Subgroup within Field of Testing 7, as identified in Section 64823, shall employ those methods found in either "Recommended Procedures for the Examination of Sea Water and Shellfish", 4th edition, 1970, American Public Health Association (APHA); or "Official Methods of Analysis of the Association of Official Analytical Chemists", 14th edition, 1984, AOAC, Arlington, Virginia. Laboratories certified in any Subgroup within Filed of Testing 15, as identified in Section 64823, shall employ methods which were submitted to the Department at time of application for certification, or at time of request to add a Subgroup within a Field of Testing and which have been approved by the Department for use in the laboratory.

(f) Laboratories may substitute alternate test methods for those allowed by (a) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be

~~utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process, or shall obtain a waiver from the Environmental Laboratory Accreditation Program (ELAP), prior to implementing any substitution. ELAP may grant a waiver when a State Maximum Contaminant Level (MCL) is more stringent than a federal MCL or no State MCL exists and when ELAP determines that the test method the laboratory proposes to use is one for which that laboratory was previously ELAP certified. A waiver shall be valid until a new State MCL is adopted for the analyte being detected by the method.~~

~~(g) Laboratories may substitute alternate test methods for those allowed by (b) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the California Environmental Protection Agency, Hazardous Materials Laboratory, Berkeley, California prior to implementing any substitutions.~~

~~(h) Laboratories may substitute alternate test methods for those allowed by (c) above. If such substitution is desired, the laboratory shall obtain written approval for the alternate test method to be utilized from the United States Environmental Protection Agency (EPA) through that agency's Alternate Test Procedure approval process prior to implementing any substitution.~~

~~(i) Laboratories seeking certification for the subgroups consisting of fecal coliform or Escherichia coli (E. coli) organism technics, must also obtain, or hold, certification for the subgroups consisting of the same technic for total coliform organisms.~~

~~(j) To gain certification for individual radioactive elements or isotopes, except for uranium by fluorimetric technics, a laboratory shall obtain certification for gross alpha and beta radiation testing.~~

~~(k) A laboratory may seek certification, or hold certification for Field of Testing 11 without seeking or holding certification in Fields of Testing 10, 12, or 13. However, the laboratory shall submit all resulting preparations from the use of any of the subgroup members of Field of Testing 11 to a laboratory certified for Fields of Testing 10, 12, or 13.~~

NOTE: Authority cited: Sections 208, 1011 and 1012, Heath and Safety Code. Reference: Sections 1012, 1017 and 28503, Health and Safety Code; Section 12901, Title 22, California Code of Regulations; Appendices I, II and III of Article 5 (commencing with Section 66261.100), Title 22, California Code of Regulations.

~~**ARTICLE 7. LABORATORY AND EQUIPMENT**~~

~~**§64813. Laboratory and Equipment.**~~

~~(a) A laboratory shall be arranged and operated so that:~~

~~(1) utilities are maintained to the degree necessary to allow the laboratory equipment to function and produce analyses in each Subgroup within each Field(s) of Testing for which the laboratory is certified;~~

~~(2) ventilation and environmental control are maintained in the laboratory so that analytical results are not adversely affected beyond establish quality control limits as specified in the approved test methods or in the laboratory's quality assurance manual;~~

~~(3) the design, arrangement, and operation of the laboratory minimizes the potential for sample contamination;~~

~~(4) the storage and handling of hazardous materials in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders, Department of Industrial Relations; and~~

~~(5) the disposal of chemical wastes is in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Wastes, State of California, Department of Health Services.~~

~~(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory.~~

~~(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory as required by the manufacturer's maintenance instructions for the equipment.~~

~~(d) Records shall be kept of all operational and maintenance activities associated with the operation of laboratory equipment.~~

NOTE: Authority cited: Sections 208, 1011 and 1012, Heath and Safety Code. Reference: Section 1012, Health and Safety Code; California Code of Regulations, Title 8; and Title 22, Division 4, Chapter 30, California Code of Regulations.

~~**ARTICLE 8. QUALITY ASSURANCE DOCUMENTS**~~

~~**§64815. Quality Assurance.**~~

~~(a) Each laboratory shall develop and implement a quality assurance program to assure the reliability and validity of the analytical data produced by the laboratory. As evidence of such a program, the laboratory shall develop and maintain a quality assurance program manual.~~

~~(b) The quality assurance program manual shall address all quality assurance and quality control practices to be employed by the laboratory and shall, at least, include the quality assurance and quality control requirements specified in the test methods for which the laboratory holds, or seeks, certification. The manual shall include the following elements: laboratory organization and personnel responsibilities; quality assurance objectives for measurement data; sampling procedures (when the laboratory performs the sampling); custody, handling, and disposal of samples; calibration procedures and frequency; analytical procedures; acquisition and reduction, validation and reporting of data; internal quality control checks; performance and system audits; preventive maintenance; assessment of precision and accuracy; corrective action; and quality assurance reports.~~

~~(c) The Laboratory Director shall review, and amend if necessary, the quality assurance program and quality assurance program manual at least annually. The Laboratory Director shall also review and amend the quality assurance program and manual whenever there are changes in methods or laboratory~~

~~equipment employed, in the laboratory structure or physical arrangements, or changes in the laboratory organization.~~

~~(d) A laboratory shall maintain records of the implementation of its quality assurance program, and provide those records upon request of the Department. Records shall be maintained for a minimum of three years.~~

NOTE: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Section 1012, Health and Safety Code.

~~**ARTICLE 9. LABORATORY PERSONNEL**~~

~~**§64817. Laboratory Personnel.**~~

~~(a) Each laboratory shall designate a Laboratory Director. Except as provided in (b) below, no person shall be designated as a Laboratory Director unless he or she meets the following educational and experience requirements.~~

~~(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science.~~

~~(2) Has at least three years experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples. The experience requirement shall be satisfied from relevant work experience prior to the person having obtained the position of Laboratory Director. A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public hearing engineering, natural or physical science may be substituted for one year of the required experience. A doctorate in chemistry, biochemistry, environmental, sanitary or public hearing engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.~~

~~(b) Laboratory Directors of utility-owned water or wastewater treatment plant laboratories performing any of the analyses required under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Laboratory Director by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:~~

~~Fields of Testing~~	~~Minimum Certificate Grade Required~~
~~1, 2* and 16**~~	~~I~~
~~1, 2, 8 and 16~~	~~II~~
~~3, 5, 17 and 19 plus those allowed for a grade II~~	~~III~~
~~4, 6, and 18 plus those allowed for a grade III~~	~~IV~~
~~* Limited to testing for: alkalinity, chloride, hardness, total filterable residue, and conductivity.~~	
~~** Limited to testing for: acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, nonfilterable residue, settleable residue, volatile residue, specific conductance, and turbidity.~~	

~~(c) All Laboratory Directors of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (a) or (b) above.~~

(d) A Laboratory Director shall be responsible for:

(1) all analytical and operational activities of the laboratory, including those of any auxiliary or mobile laboratory facilities; and

(2) supervision of all personnel employed by the laboratory, including those assigned to work in any auxiliary or mobile laboratory facilities, and those persons designated as Principle Analysts; and

(3) the accuracy and quality of all data reported by the laboratory, including any auxiliary or mobile laboratory facilities.

(e) If, for any reason, a Laboratory Director leaves and is not replaced within 15 days by a person meeting the requirements specified in (a) or (b), whichever applies, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies the Department, pursuant to Section 1014(d) of the Health and Safety Code, describing the qualifications of the temporary director and receives written confirmation from the Department. An additional extension of no more than ninety days beyond the original 90-day period may be granted by the Department, provided the laboratory can document that its good-faith efforts to recruit a qualified director were unsuccessful for reason beyond its control.

(f) A Laboratory Director shall assume the position of, or shall designate another person as Principal Analyst whenever there is use of a sophisticated laboratory instrument as defined in Section 64801(k). No person shall be a Principal Analyst for a laboratory unless he or she is:

(1) the user of the sophisticated laboratory instrument; or

(2) the supervisor of the users of the sophisticated laboratory instrument.

(g) Except as provided in (h) below, no person shall be a Principal Analyst unless he or she meets the following educational and experience requirements.

(1) Possesses at least a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or public health engineering, natural or physical science; or

(2) Possesses a certification of participation in, and completion of, a course taught by the manufacturer of the particular sophisticated laboratory instrument which is being used or supervised by the Principal Analyst; and

(3) Has at least six months experience in the operation of a sophisticated laboratory instrument in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples, or food. This experience requirement must be satisfied from experience gained prior to obtaining the position of Principal Analyst.

(h) Principal Analysts of utility-owned water or wastewater treatment plant laboratories performing any analyses under Section 4025 of the Health and Safety Code, or Section 13176 of the Water Code may fulfill the requirements for Principal Analyst by possession of a Laboratory Analyst/Water Quality Analyst Certificate from the California Water Pollution Control Association (CWPCA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA). The minimum grade of the above certificate acceptable to the Department shall be based on the Fields of Testing for which the laboratory seeks certification as noted in the conversion table set out below:

Fields of Testing	Minimum Certificate Grade Required
1, 2 and 16	I
8 plus those allowed for a grade I	II
3, 5, 17 and 19 plus those allowed for a grade II	III
4, 6, and 18 plus those allowed for a grade III	IV

(i) All Principal Analysts of laboratories certified by the Department as of December 31, 1994 shall be exempt from meeting the requirements of (g) or (h) above.

NOTE : Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Section 1012, Health and Safety Code.

ARTICLE 10. NOTIFICATION AND REPORTING

§64819. Notification and Reporting.

(a) Laboratories certified for Field of Testing 1, 2, 3, 4, 5, or 6 shall conform to the following reporting and notification requirements.

(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.

(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:

(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.

(B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).

(C) A nitrate sample exceeds the MCL.

(3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraphs (2)(A) or (C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.

(4) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001, by the 10th day of the month following the month in which the analyses were completed.

(5) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:

(A) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;

(B) complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;

(C) complete description of the error alleged to have invalidated the result(s);

(D) copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and

(E) any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.

(b) Laboratories certified for Fields of Testing 20, 21, or 22 shall verify the identity and quantity of a pesticide residue before reporting the results. The confirmation procedures must conform to those in Section 64811(d) of this Chapter.

~~(c) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) prepared by all other laboratories who are party to the agreement.~~

NOTE: Authority cited: Sections 100275, 100830, 100835 and 116375, Health and Safety Code. Reference: Sections 100825(b) and 100835, Health and Safety Code.

~~ARTICLE 11. RECIPROCITY AGREEMENTS~~

~~§64821. Reciprocity Agreements.~~

~~(a) Another State's, or a United States agency's environmental laboratory certification, accreditation, or licensing program shall be recognized for the purposes of reciprocity if the program requires:~~

~~(1) periodic analyses of performance evaluation samples by the participating laboratories with the frequency of submittal, the method of evaluation, and the established acceptance limits at least equal to those established in Section 64809 of this Chapter;~~

~~(2) on-site evaluation of participating laboratories during which the laboratory is reviewed under criteria at least equal to that established in Section 64807 of this Chapter;~~

~~(3) standards for quality assurance, laboratory facilities, test methods, laboratory equipment, and personnel for participating laboratories at least equal to those in Sections 64811, 64813, 64815, and 64817 of this Chapter.~~

~~(b) Where reciprocity exists, each laboratory seeking California certification shall submit:~~

~~(1) an application pursuant to Section 64805(a) of this Chapter;~~

~~(2) copies of the results evaluated, or scored, from the last performance evaluation sample testing conducted by the laboratory for the other program;~~

~~(3) copies of the last on-site evaluation report prepared by the other program and the laboratory's response to any deficiencies noted;~~

~~(4) all applicable fees pursuant to Health and Safety Code, Section 1017(a); and~~

~~(5) a copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other agency.~~

~~(c) When a reciprocity agreement exists between the Department and another State, only those laboratories that reside within the boundaries of the other State shall be eligible for certification through reciprocity.~~

~~(d) If a reciprocity agreement with another State, or U.S. government agency is revoked, all certificates issued by the Department to all affected laboratories shall remain valid until the stated expiration date.~~

~~(e) No fees are waived where reciprocity exists.~~

~~(f) A laboratory certified under reciprocity may be visited or issued performance evaluation samples by the Department for the purposes of addressing questions or concerns on quality of results raised by any California government agency who has received a report from the laboratory. Applicable performance evaluation sample costs, pursuant to Section 1017(f) or travel costs pursuant to Section 1017(b) of the Health and Safety Code shall be paid.~~

NOTE: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1011 and 1017, Health and Safety Code.

ARTICLE 12. SUBGROUPS FOR FIELDS OF TESTING

§64823. Fields of Testing.

(a) Field of Testing 1 consists of those methods whose purpose is to detect the presence of microorganisms in the determination of drinking water or wastewater quality and encompasses the following Subgroups: detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Multiple Tube Fermentation technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by Membrane Filter technics; Heterotrophic Plate Count technics; detection of both total coliforms and Escherichia coli (E. coli) organisms by the Minimal Medium ortho-nitrophenyl-beta-D-galactopyranoside - 4-methylumbelliferyl-beta-D-glucuronide (MMO-MUG) technics; detection of total coliform, fecal coliform, or Escherichia coli (E. coli) organisms by use of Clark's Presence/Absence medium; Fecal streptococci and Enterococci by Multiple Tube Fermentation technics, Fecal streptococci and Enterococci by Membrane Filter technics; detection of total coliforms and fecal coliforms other than for drinking water or wastewater quality.

(b) Field of Testing 2 consists of those analytes or methods whose purpose is to detect the presence of inorganic substances in the determination of drinking water quality and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technic; and encompasses the following Subgroups: alkalinity; calcium (titrimetric technics); chloride; corrosivity; fluoride; hardness (direct determination); magnesium (titrimetric technics); methylene blue active substances (MBAS); nitrate; nitrite; sodium (flame emission technics); sulfate; total filterable residue and conductivity; iron; manganese; orthophosphate; silica; cyanide; potassium (flame emission technics).

(c) Field of Testing 3 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of drinking water quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: arsenic; barium; cadmium; total chromium; copper; iron; lead; manganese; mercury; selenium; silver; zinc; aluminum; asbestos; antimony; beryllium; nickel; thallium; calcium; magnesium; sodium; potassium.

(d) Filed of Testing 4 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 524.2 for volatile organics; EPA method 501.3 for trihalomethanes; EPA method 525 for acid and base/neutral compounds; EPA method 513 for dioxins; EPA method 1613 for dioxins.

(e) Field of Testing 5 consists of those methods whose purpose is to detect the presence of trace organics in the determination of drinking water quality and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 501.1 for trihalomethanes; EPA method 501.2 for trihalomethanes; EPA method 510 for total trihalomethanes; EPA method 508 for chlorinated pesticides; EPA method 515.1 for chlorophenoxy herbicides; EPA method 502.1 for halogenated volatiles; EPA method 503.1 for aromatic volatiles; EPA method 502.2 for both halogenated and aromatic volatiles; EPA method 504 for EDB and DBCP; EPA method 505 for chlorinated pesticides and ploychlorinated biphenyls; EPA method 507 for the haloacids; EPA method 531.1 for carbamates; EPA method 547 for glyphosate; EPA method 506 for adipates and phthalates; EPA method 508A for total polychlorinated biphenyls; EPA method 548 for endothall; EPA method 549 for diquat and paraquat; EPA method 550 for polycyclic aromatic hydrocarbons; EPA method 550.1 for polycyclic aromatic hydrocarbons; EPA method 551 for chlorination disinfection byproducts; EPA method 552 for haloacetic acids.

~~(f) Field of Testing 6 consists of those methods whose purpose is to detect the presence of radioactive substances in drinking water, wastewater, or hazardous wastes; and encompasses the following Subgroups: gross alpha and beta radiation; total radium; radium 226; uranium; radon 222; radioactive cesium; iodine 131; radioactive strontium; tritium; gamma emitting isotopes; gross alpha by coprecipitation; radium 228; radioactive iodine; gross alpha and beta radiation in hazardous wastes; alpha emitting radium isotopes in hazardous wastes; radium 228 in hazardous wastes.~~

~~(g) Field of Testing 7 consists of those methods whose purpose is to detect the presence of microbial contamination or toxins in the determination of shellfish meat quality and encompasses the following Subgroups: shellfish meat microbiology; paralytic shellfish poison (PSP) and other marine biotoxins; microbiology of shellfish growing waters.~~

~~(h) Field of Testing 8 consists of those methods whose purpose is to detect the presence of toxins in the determination of wastewater quality, or in hazardous wastes and encompasses the following Subgroups: hazardous waste testing pursuant to Title 22, California Code of Regulations, Section 66261.24(a)(6); wastewater testing according to Kopperdahl (1976) using freshwater fish; wastewater testing according to EPA/600/4-85/013 using freshwater and/or marine organisms; wastewater testing by EPA method 1000.0; wastewater testing by EPA method 1002.0; wastewater testing by EPA method 1003.0; wastewater testing by EPA method 1006; wastewater testing by EPA method 1007; wastewater testing by EPA method 1009; wastewater testing according to Anderson, et al. (1990) using Giant Kelp (Macrocystis pyrifera); wastewater testing according to Anderson, et al. (1990) using red abalone (Haliotus rufescens); wastewater testing according to Dinnel and Stober (1987) using purple sea urchin (Strongylocentrotus purpuratus); wastewater testing according to Dinnel and Stober (1987) using red sea urchin (Strongylocentrotus franciscanus); wastewater testing according to Dinnel and Stober (1987) using sand dollar (Dendraster excentricus); wastewater testing according to procedure E 724-89 (ASTM, 1989) using Pacific oyster (Crassostrea gigas); wastewater testing according to procedure E 724-89 (ASTM, 1989) using California Bay Mussel (Mytilus edulis); wastewater testing according to procedure E 1218-90 (ASTM, 1990) using an alga (skeletonema costatum); wastewater testing according to EPA/600/4-90/027 using freshwater and/or marine organisms.~~

~~(i) Field of Testing 9 consists of those methods whose purpose is to detect physical properties of hazardous wastes for regulatory purposes and encompasses the following Subgroups: ignitability; corrosivity by pH determination; corrosivity by corrosivity towards steel; reactivity.~~

~~(j) Field of Testing 10 consists of those methods whose purpose is to detect the presence of inorganic substances in hazardous waste samples and encompasses the following Subgroups: antimony; arsenic; barium; beryllium; cadmium; chromium, total; cobalt; copper; lead; mercury; molybdenum; nickel; selenium; silver, thallium; vanadium; zinc; chromium (VI); cyanide; fluoride; sulfide; total organic lead.~~

~~(k) Field of Testing 11 consists of those methods whose purpose is to prepare samples of hazardous wastes for further testing and encompasses the following Subgroups: California waste extraction test (WET); extraction procedure toxicity (EP TOX); toxicity characteristic leaching procedure (TCLP), all phases; TCLP, extraction of inorganics only; TCLP, extraction of semivolatile organics only; TCLP, extraction of volatile organics only.~~

~~(l) Field of Testing 12 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8240 for volatile compounds; EPA method 8250 for semivolatile compounds; EPA method 8270 for semivolatile compounds; EPA method 8280 for dioxins, EPA method 8290, EPA method 8260.~~

(m) Field of Testing 13 consists of those methods whose purpose is to detect the presence of trace organics in hazardous waste samples, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 8010 for halogenated volatiles; EPA method 8015 for nonhalogenated volatiles; EPA method 8020 for aromatic volatiles; EPA method 8030 for acrolein, acrylonitrile, acetonitrile; EPA method 8040 for phenols; EPA method 8060 for phthalate esters; EPA method 8080 for organochlorine pesticides or polychlorinated biphenyls; EPA method 8090 for nitroaromatics and cyclic ketones; EPA method 8100 for polynuclear aromatic hydrocarbon; EPA method 8130 for polynuclear aromatic hydrocarbons; EPA method 8120 for chlorinated hydrocarbons; EPA method 8140 for organophosphorus pesticides; EPA method 8150 for chlorinated herbicides; EPA method 632 for carbamates; total petroleum hydrocarbons - gasoline (LUFT manual); total petroleum hydrocarbons - diesel (LUFT manual); EPA method 8011; EPA method 8021; EPA method 8070; EPA method 8110; EPA method 8141; EPA method 8330; EPA method 8080 for PCBs only; EPA method 8080 for chlorinated pesticides only.

(n) Field of Testing 14 consists of those methods whose purpose is to detect the presence of asbestos for purposes of complying with the provisions of Title 22, California Code of Regulations, Section 66261.24(a)92)(A) and encompasses the following Subgroups: asbestos by polarized light microsopy.

(o) Field of Testing 15 shall be any method whose purpose is to detect the presence of any analyte found in the list of substances regulated by the California Safe Drinking Water and Toxic Enforcement Act in drinking water, wastewater, hazardous wastes, and contaminated soils or sediments, but which method is not within any subgroup of any other Field of Testing cited in this section.

(p) Field of Testing 16 consists of those methods whose purpose is to detect the presence of inorganic substances, nutrients, physical or chemical demands, or physical properties in the determination of wastewater quality, and whose methods require the use colorimetric, gravimetric, titrimetric, electrometric, or ion chromatographic technics and encompasses the following Subgroups: acidity; alkalinity (includes determination of bicarbonate, carbonate, & hydroxide); ammonia; biochemical oxygen demand (BOD); boron; bromide; calcium (titrimetric technics); carbonaceous biochemical oxygen demand (cBOD); chemical oxygen demand (COD); chloride; chlorine residual, total; cyanide; cyanide amenable to chlorination; fluoride; hardness (direct determination); kjeldahl nitrogen (includes determination of organic nitrogen); magnesium (titrimetric technics); nitrate; nitrite; oil and grease; organic carbon; oxygen, dissolved, pH; phenols; phosphate ortho; phosphorus, total; potassium (flame emission technics); residue, total; residue, filterable (total dissolved solids); residue, nonfilterable (total suspended solids); residue, settleable (settleable solids); residue, volatile; silica; sodium (flame emission technics); specific conductance; sulfate; sulfide (includes total and soluble); sulfite; surfactants (MBAs); tannin and lignin; turbidity; iron; manganese; total recoverable hydrocarbons by EPA method 418.1; total organic halides.

(q) Field of Testing 17 consists of those methods whose purpose is to detect the presence of trace metals, or asbestos in the determination of wastewater quality and whose methods require the use of an atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or electron microscope device and encompasses the following Subgroups: aluminum; antimony; arsenic; barium; beryllium; cadmium; chromium (VI); chromium, total; cobalt; copper; gold; iridium; iron; lead; manganese; mercury; molybdenum; nickel, osmium; palladium; platinum; rhodium; ruthenium; selenium; silver; strontium; thallium; tin; titanium; vanadium; zinc; asbestos; calcium; magnesium; potassium; sodium.

(r) Field of Testing 18 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 624 for volatile organics; EPA method 625 for acid and base/neutral compounds; EPA method 1613 for dioxins; EPA method 1625 for dioxins; EPA method 613.

(s) Field of Testing 19 consists of those methods whose purpose is to detect the presence of trace organics in the determination of wastewater quality, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompasses the following Subgroups: EPA method 601 for halogenated volatiles; EPA method 602 for aromatic volatiles; EPA method 603 for acrolein, acrylonitrile, acetonitrile; EPA method 604 for phenols; EPA method 605 for benzidine; EPA method 606 for phthalate esters; EPA method 607 for nitrosoamines; EPA method 608 for organochlorine pesticides or polychlorinated biphenyls; EPA method 609 for nitroaromatics and cyclic ketones; EPA method 610 for polynuclear aromatics; EPA method 612 for haloethers; EPA method 632 for carbamates; EPA method 619; EPA method 608 for PCBs only; EPA method 608 for chlorinated pesticides only.

(t) Field of Testing 20 consists of those methods whose purpose is to detect the presence of inorganic pesticide residues in raw agricultural or bulk processed food and encompasses the following Subgroups: pesticide residues in processed foods detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in raw commodities detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in dairy products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass spectrophotometer, or colorimetric technics; pesticide residues in feed products detected by either atomic absorption, inductively coupled plasma, inductively coupled plasma/mass-spectrophotometer, or colorimetric technics.

(u) Field of Testing 21 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: chromatographic/mass spectrophotometric methods in either processed foods; raw commodities; dairy products; feed products.

(v) Field of Testing 22 consists of those methods whose purpose is to detect the presence of organic pesticide residues in raw agricultural or bulk processed food, and do not require the use of a gas chromatographic/mass spectrophotometric device and encompass the following Subgroups: halogenated compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in processed foods detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in raw commodities detected by either gas chromatograph, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in raw commodities detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid

~~chromatography/mass spectrophotometry technics; carbamates in dairy products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; halogenated compounds in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; organophosphorous compounds in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics; carbamates in feed products detected by either gas chromatography, high pressure liquid chromatography, or liquid chromatography/mass spectrophotometry technics.~~

~~(w) Field of Testing 23 consists of the subgroup members appropriate to the Field of Testing stated by the laboratory, pursuant to Section 64805(b)(1).~~

NOTE: Authority cited: Sections 208 and 1011, Health and Safety Code. Reference: Sections 1012, 1013, 1015, 1017 and 1019, Health and Safety Code.

~~ARTICLE 4~~ 13. TRADE SECRETS

~~§64825. Trade Secrets.~~

~~(a) If a laboratory identifies information provided to the Department as a trade secret, the Department shall not release such information lunless:~~

~~(1) the release is authorized under state or federal law; and~~

~~(2) the Department has notified the laboratory of the impending release. Such notification shall be at least ten days prior to releasing any information identified as a trade secret, stating the name of the party requesting the information, the reason for the request, the authority to release this information, and the date the information will be released.~~

NOTE: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Sections 1012 and 1013, Health and Safety Code; Section 6254.7(d), Government Code.

~~ARTICLE 14. SALE OR TRANSFER OF OWNERSHIP OF A LABORATORY~~

~~§64827. Sale or Transfer of Ownership.~~

~~(a) A certificate shall be voided by operation of law if one or more of the following occurs.~~

~~(1) An original Owner fails to notify the Department, in writing, within 15 days after a change in ownership.~~

~~(2) A new Owner relocates the laboratory within 90 days of assuming ownership.~~

~~(3) If more than half the number of laboratory persons either quit or are terminated and replaced by a new Owner within 90 days of assuming ownership.~~

~~(4) If a new Owner submits an application to alter the laboratory's certificate as issued to the prior Owner by the addition of any Subgroup within any Field of Testing.~~

~~(b) A new Owner of a laboratory shall notify the Department, in writing, within 15 days after the sale or transfer of ownership and provide, at minimum, the following information.~~

~~(1) The name(s) of the new Owner(s).~~

~~(2) The date of sale or transfer of ownership.~~

~~(3) The name, education and laboratory related work experiences, as specified in Section 64817(a); or voluntary laboratory certificate grade as specified in Section 64817(b), of the person designated as the Laboratory Director.~~

(4) The names, education and laboratory related work experiences, as specified in Section 64817(g); or voluntary laboratory certificate grade as specified in Section 64817(h), of all persons who are designated as Principal Analysts.

(5) The names of all Principal Analysts who have quit, or were terminated and replaced; and the names of all Principal Analysts hired as replacements.

(6) A statement that there will be no changes in laboratory location, or in the certificate issued to the prior Owner(s) within 90 days of assuming ownership.

(7) A statement that all equipment, method, and quality assurance practices will not change within 90 days of assuming ownership.

(8) The notice shall be signed by one or more of the new Owner(s), or their Agents.

(c) New Owners that comply with the provisions of (b) above shall have use of the certificate issued to the prior Owner for a period of ninety days commencing with the date of the Department's notice of receipt of the information supplied by the new Owner.

(1) The certificate number and the laboratory name appearing on the certificate shall remain the same.

(2) The new Owner shall display, and provide a copy with all data reports, the Department's notice recognizing the sale or transfer of ownership.

(d) To obtain the use of the certificate to its original expiration date, the new Owner shall request such use in writing, and the laboratory shall be subjected to, and pass the following, within the 90 days use period granted by the Department.

(1) A site visit in accordance with Section 64807; and

(2) Performance evaluation samples in accordance with Section 64809.

NOTE: Authority cited: Sections 208, 1011 and 1012, Health and Safety Code. Reference: Section 1014, Health and Safety Code.

ARTICLE 16. NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION PROGRAM (NELAP)

§64860. NELAP Accreditation Fees.

(a) The following schedule of fees shall apply to every environmental laboratory applying for an initial, amendment, or renewal of a National Environmental Laboratory Accreditation Program (NELAP) primary or secondary accreditation:

(1) A non-refundable application fee of $3,000 payable at the time of initial and renewal application for accreditation, and

(2) An additional non-refundable fee for each Field of Testing specified in Health and Safety Code Section 100862 which the laboratory has requested in its application, payable at the time of application for an initial, amended, or renewed NELAP accreditation, as follows:

(A) A fee of $750 for each low complexity Field of Testing, identified as Fields of Testing number N115, N120, and N121.

(B) A fee of $1000 for each medium complexity Field of Testing, identified as Field of Testing number N101, N102, N103, N106, N107, N108, N109, N112, N114, and N118.

(C) A fee of $1,800 for each high complexity Field of Testing, identified as Field of Testing number N104, N105, N110, N111, N113, N116, N117 and N119.

(b) No environmental laboratory shall be approved as a NELAP accredited laboratory until fees provided by this section have been paid.

NOTE: Authority cited: Sections 100830, 100835(a) and 100862, Health and Safety Code. Reference: Section 100825, Health and Safety Code.

ARTICLE 1. DEFINITIONS.
§64801.05. Acceptable Results.
§64801.10. Analytical Specialist.
§64801.15. California Analyte.
§64801.20. Deficiency.
§64801.23. Demonstration of Technical Capability.
§64801.25. Designated Analyte.
§64801.30. ELAP.
§64801.35. Environmental Sample.
§64801.40. Facilities.
§64801.45. Field of Accreditation or FoA.
§64801.50. Interim Certificate.
§64801.55. Laboratory Director.
§64801.60. Not Acceptable.
§64801.65. Owner.
§64801.70. Owner's Agent or Agents of Owners.
§64801.75. State Regulatory Program.
§64801.80. Test Method.
§64801.85. Unit of Accreditation or UoA.

ARTICLE 2. Accreditation Process for ELAP and NELAP.
§64803. Basic Accreditation Requirements for ELAP and NELAP.
§64804. Application for ELAP and NELAP Certificates.
§64805. Accreditation Fees for ELAP and NELAP Certificates.
§64806. Fields of Accreditation (FoAs).

ARTICLE 3. NELAP Accreditation Requirements.
§64807. Requirements for NELAP Certificates.

ARTICLE 4. ELAP Accreditation Requirements.
§64808. Proficiency Testing (PT) Studies.
§64809. On-Site Assessment.
§64810. Reciprocity Agreement.
§64811. Change of Laboratory Ownership.
§68412. Laboratory and Equipment.
§64813. Quality Assurance.
§64814. Laboratory Personnel.
§64815. Notification, Reporting, and Records Retention.

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ARTICLE 1. DEFINITIONS.

§64801.05. Acceptable Results.

"Acceptable Results" means PT study findings that the PT study provider or ELAP has determined meet acceptance criteria specified for the study undertaken.

§64801.10. Analytical Specialist.
"Analytical specialist" means a person who either supervises the activities of others in, or conducts, the analyses of environmental samples using sophisticated laboratory instruments, such as gas chromatograph/mass spectrometers (GC/MS), inductively coupled plasma atomic emission spectrometers (ICP-AES), inductively coupled plasma mass spectrometers (ICP-MS), liquid chromatograph/mass spectrometers (LC-MS), atomic absorption spectrophotometers (AA), gas chromatographs (GC), alpha particle or gamma ray spectrophotometer, electron microscopes (EM), polarized light microscope (PLM), high pressure liquid chromatographs (HPLC), or liquid scintillation counter (LSC).

§64801.15. California Analyte.
"California analyte" means a chemical or substance for which monitoring is required by a State regulatory program, but may not be by any federal government program.

§64801.20. Deficiency.
"Deficiency" mean a deviation from test method procedures or practices that has not been authorized by ELAP.

§64801.23. Demonstration of Technical Capability.
"Demonstration of technical capability" means a document that provides to ELAP the information necessary to determine whether a laboratory has the capability to conduct the analysis for a specific UoA, including:

(a) Documentation that the laboratory has the necessary equipment/instrumentation;

(b) Documentation describing the laboratory's operating procedures to ensure conformance with the analytical method(s);

(c) Four replicates analysis of quality control samples, as follows:

(1) Samples obtained from the external source of the initial calibration standards;

(2) An evaluation of accuracy (mean) and precision (standard deviation); and

(3) Quality control sample concentration as specified in the method or, if unspecified, approximately ten times the laboratory-calculated MDL;

(d) Method detection limit study according to 40 CFR Part 136, Appendix B (if required by the method); and

(e) Initial calibration results (if required by the method).

§64801.25. Designated Analyte.
"Designated analyte" means a substance that can occur in the materials regulated by a State regulatory program that requires the analysis of environmental samples by accredited laboratories.

§64801.30. ELAP.
"ELAP" means the California Environmental Laboratory Accreditation Program.

§64801.35. Environmental Sample.

"Environmental sample" means a collected volume of potable or not-potable surface or ground water, soil, sediment, hazardous waste, or any other material analyzed for a State regulatory program.

§64801.40. Facilities.
"Facilities" means fixed or portable building(s), including storage areas, that contain the analytical and ancillary operating equipment, supplies and space necessary to perform the analyses in the FoAs for which a laboratory is accredited.

§64801.45. Field of Accreditation or FoA.
"Field of Accreditation" or "FoA" means a group of UoAs.

§64801.50. Interim Certificate.
"Interim certificate" means a temporary certificate of accreditation listing UoAs that a laboratory has requested be added to its existing certificate, that allows the laboratory to report analyses for regulatory purposes for the additional UoAs.

§64801.55. Laboratory Director.
"Laboratory director" means the laboratory staff person who is responsible for actual day-to-day supervision of all technical, analytical and data reporting operations in the laboratory for the fields of accreditation listed on the laboratory's certificate.

64801.60. Not Acceptable.
"Not Acceptable" means that the PT study provider or ELAP has determined that the PT study findings do not meet acceptance criteria specified for the study undertaken.

§64801.65. Owner.
"Owner" means any person who is a sole proprietor of a laboratory, or any person who holds a partnership interest in a laboratory, or any person who is an officer, or 5% (five percent) or more shareholder in a corporation which owns a laboratory.

§64801.70. Owner's Agent or Agents of Owners.
"Owner's agent" or "agents of owners" means those persons who have been designated by the Owner(s) of the laboratory to act in its behalf for purposes of complying with this chapter or the statutes under which this chapter has been adopted.

§64801.75. State Regulatory Program.
"State regulatory program" means a program that requires the analysis of environmental samples that has been established under regulatory and/or statutory requirements by the State Water Resources Control Board (SWRCB), Regional Water Quality Control Boards (RWQCBs), the Department of Toxic Substances Control (DTSC), the California Environmental Protection Agency (Cal/EPA), the Department of Health Services (DHS), the Department of Food and Agriculture (DFA), or any successor agencies.

§64801.80. Test Method.

"Test method" means an analytical testing technique or procedure that a State regulatory program requires to be used to determine the level of a designated analyte in an environmental sample for the purposes of assessing compliance with its statutes, regulations and/or permits.

§64801.85. Unit of Accreditation or UoA.

"Unit of accreditation" or "UoA" means a specific combination of: (a) for ELAP accreditation, a State regulatory program, or for NELAP accreditation, a matrix, (b) a test method or technology, and (c) a designated analyte or analyte group for which accreditation may be obtained.

ARTICLE 2. Accreditation Process for ELAP and NELAP.

§64803. Basic Accreditation Requirements for ELAP and NELAP.

(a) To obtain a certificate of accreditation (certificate), a laboratory shall meet the following requirements:

(1) Submit an application, pursuant to Section 64804;

(2) Except for interim and reciprocal certificates, complete an on-site assessment, pursuant to Section 64808 for ELAP accreditation or NELAC Standards for NELAP accreditation;

(3) Achieve Acceptable Results in the required proficiency testing studies (PT studies) pursuant to Section 64808 for ELAP accreditation or NELAC Standards for NELAP accreditation; and

(4) Pay the required fees pursuant to Section 64805.

(b) The period of the certificate shall be based on the anniversary of the initial certificate of accreditation and shall be as follows:

(1) For an ELAP certificate, two years;

(2) For a NELAP certificate, twelve months, and

(3) For an amended ELAP or NELAP certificate, the time remaining on the certificate from the date it was amended.

(c) To renew a certificate, at least ninety days prior to its expiration date, a laboratory shall submit a renewal application pursuant to Section 64804(a).

(1) If the application is submitted less than 90 days prior to, but not after, the certificate expiration date, the laboratory shall pay a late fee of $300 in addition to its accreditation fee.

(2) If it does not submit its renewal application by the certificate expiration date, as of that date, the laboratory shall cease all reporting of analytical work for regulatory purposes until it has been notified in writing that its application has been received by ELAP. When it submits its renewal application, the laboratory shall pay a penalty in addition to its accreditation fee as follows:

(A) 10% of its accreditation fee, if application submitted within 30 days after the expiration date;

(B) 25% of its accreditation fee, if application submitted 31 to 60 days after the expiration date; or

(C) 50% of its accreditation fee, if application submitted 61 to 90 days after the expiration date.

(3) If a laboratory fails to submit its renewal application by 90 days after its certificate expiration date, the certificate shall not be renewable. To obtain a certificate, the laboratory shall be required to apply as for an initial certificate, pursuant to Subsection (a).

(4) A laboratory that has submitted a renewal application shall be subject to an on-site assessment within six months after being notified by ELAP of the requirement for the assessment. If the assessment is not completed within this time period and the delay is not due to ELAP error or procedure, the laboratory's certificate shall be subject to revocation.

§64804. Application for ELAP and NELAP Certificates.

(a) To apply for an initial, renewed, or amended ELAP or NELAP certificate, a laboratory shall submit an application to ELAP that includes the following:

(1) Details on the laboratory's type, location, contact information and ownership;

(2) Qualifications of personnel, addressing the requirements in Section 64812:

(A) For an ELAP certificate, Laboratory Director and Analytical Specialist(s); or

(B) For a NELAP certificate, Technical Director and Quality Assurance Officer;

(3) FoA(s) and/or UoA(s) for which accreditation is being requested;

(4) Quality assurance manual pursuant to Section 64813 for ELAP accreditation and NELAC Standards for NELAP accreditation;

(5) Fees, pursuant to Section 64805 and, for renewals, Subsection 64803(c); and

(6) Signature of the Laboratory Owner and date signed.

(b) A laboratory may submit a written request at any time for an interim certificate, if it is an accredited laboratory that is applying for an amended certificate to add UoAs and wishes to report analyses for regulatory purposes for the new UoAs while its amendment application is being processed. A laboratory shall not submit a request for an interim certificate for a microbiological test procedure, unless it is already accredited for one or more equivalent microbiological methods.

(1) Prior to the laboratory's conducting and/or reporting any analytical work for regulatory purposes, Acceptable Results for PT studies for the UoAs in the application shall be received by ELAP and an interim certificate issued.

(2) The interim certificate shall be valid until:

(A) A site visit has been completed and an amended certificate issued; or

(B) An amended certificate has been issued based on ELAP's review of an equivalent demonstration of technical capability by the laboratory for the UoAs on its application.

(C) ELAP notifies the laboratory that the interim certificate has expired due to failure to meet either of the requirements in (b)(2)(A) or (B) or at the end of one year from its issue date, whichever comes first.

(c) To remove one or more UoAs or FoAs from its certificate:

(1) In between renewals, the laboratory shall submit a written request to ELAP and receive an amended certificate.

(2) At the time of renewal, the laboratory shall indicate the requested changes on its renewal application.

§64805. Accreditation Fees for ELAP and NELAP Certificates.

(a) Fees for ELAP accreditation shall be paid as follows:

(1) An administrative fee of $1250 with the submittal of an application for initial, renewed, or reinstated accreditation, and annually thereafter;

(2) An FoA fee determined as follows with the submittal of an application for initial, amended, renewed, or reinstated accreditation, and annually thereafter:

(A) $500 each for FoAs 102, 109, 115, and 119;

(B) $750 each for FoAs 101, 103, 105, 107, 108, 110, 112, 113, 116, 118, 120, 121, 122, and 123; and

(C) $1100 each for FoAs 104, 106, 111, 114, 117, and 124.

(3) A UoA fee of $5 for each UoA (single analyte) listed on the application for initial, amended, renewed, or reinstated accreditation, and annually thereafter. If a laboratory seeks accreditation for an analyte group by a single method, the total UoA fee for the group shall be reduced by 25 percent.

(b) Fees for NELAP accreditation shall be paid as follows:

(1) An administrative fee of $3000 with the submittal of an application for initial, renewed, or reinstated accreditation, and annually thereafter;

(2) An FoA fee determined as follows with the submittal of an application for initial, amended, renewed, or reinstated accreditation, and annually thereafter:

(A) $750 each for FoAs 102, 109, 115, and 119;

(B) $1000 each for FoAs 101, 103, 105, 108, 110, 112, 113, 116, 118, 120, and 121; and

(C) $1200 each for FoAs 104, 106, 111, 114, and 117.

(3) A UoA fee of $5 for each UoA (single analyte or group) listed on the application for initial, amended, renewed, or reinstated accreditation, and annually thereafter. If a laboratory seeks accreditation for an analyte group by a single method, the total UoA fee for the group shall be reduced by 25 percent.

(c) When the new owner of a laboratory that has changed ownership requests to retain the ELAP or NELAP certificate, it shall submit FoA fees pursuant to Section 64805 for the FoAs on the certificate.

§64806. Fields of Accreditation (FoAs).

Pursuant to Subsection 64804(a)(3), a laboratory shall specify the individual units of accreditation (UoAs) within the Fields of Accreditation (FoAs) in Table 64806-A.

Table 64806-A
Fields of Accreditation

FoA #	***FoA Names***	
	Regulatory Program	***Description***
101	DHS	Microbiology
102	DHS	General Physical and Inorganic Tests
103	DHS	Spectroscopy and Ion Chromatography

104	DHS	Liquid and Gas Chromatography
105	DHS	Radiochemical Techniques
106	DHS	Microscopy
107	DHS	Microbiology of Shellfish
108	SWRCB/RWQCB	Microbiology
109	SWRCB/RWQCB	General Physical and Inorganic Tests
110	SWRCB/RWQCB	Spectroscopy and Ion Chromatography
111	SWRCB/RWQCB	Liquid and Gas Chromatography
112	SWRCB/RWQCB	Radiochemical Techniques
113	SWRCB/RWQCB	Aquatic Toxicity Bioassay
114	SWRCB/RWQCB	Microscopy
115	DTSC	General Physical and Inorganic Tests
116	DTSC	Spectroscopy and Ion Chromatography
117	DTSC	Liquid and Gas Chromatography
118	DTSC	Radiochemical Techniques
119	DTSC	Sample Preparation Techniques
120	DTSC	Microscopy
121	DTSC	Aquatic Toxicity Bioassay
122	CDFA	Environmental Microbiology of Food
123	CDFA	Spectroscopy and Ion Chromatography
124	CDFA	Liquid and Gas Chromatography

ARTICLE 3. NELAP Accreditation Requirements.

§64807. Requirements for NELAP Certificates.

Unless otherwise specified in this Chapter, a laboratory applying for NELAP accreditation shall comply with the NELAC Standards.

ARTICLE 4. ELAP Accreditation Requirements.

§64808. Proficiency Testing (PT) Studies.

(a) If a PT study that meets the requirements in Subsection (c)(2)(A and B) is available, to obtain an initial or amended ELAP certificate, each laboratory shall achieve Acceptable Results for at least one PT study for each UoA on its application within three months prior to, or subsequent to, the Department's receipt of the laboratory's application.

(1) Each laboratory shall not conduct more than two PT studies for each UoA, with the exception of UoAs in FoAs 122, 123, and 124;

(2) If it does not achieve Acceptable Results in the first PT study for a UoA, each laboratory shall conduct a second study such that the closing day of the first study and the first day of the second study are at least fifteen days apart and the study is completed by the end of the next calendar quarter;

(3) If it does not achieve Acceptable Results in either of the two PT studies for a UoA, the laboratory shall not be accredited for that UoA.

(b) To maintain accreditation, each laboratory shall:

(1) For existing accredited laboratories, by November 1, 2005, and for laboratories with new certificates, within 30 days of being accredited, submit a PT study schedule to ELAP for approval that:

(A) Specifies up to two quarters within which the required PT studies will be conducted each calendar year following the year the laboratory was initially accredited for the UoA; and

(B) Is updated and resubmitted to ELAP whenever the laboratory's certificate is amended or the laboratory wishes to request a change in the schedule.

(2) Annually achieve Acceptable Results in a PT study for each UoA for which it is accredited, as follows:

(A) If the results for the first PT study for a UoA are Not Acceptable, the laboratory shall:

1. Within 30 days of receipt of the evaluation report from the PT study provider, take corrective action(s), maintain records of such actions, and notify ELAP in writing that corrective actions have been taken to improve future data quality; and

2. Conduct a second PT study such that the closing day of the first study and the first day of the second study are at least fifteen days apart and the study is completed by the end of the next calendar quarter.

(B) If the results for both PT studies for a UoA are Not Acceptable, the laboratory shall

1. Have its accreditation for that UoA suspended;

2. Cease all analytical work for regulatory purposes for that UoA upon receipt of the "Not Acceptable" results;

3. Conduct two sets of PT studies for the UoA by the end of the next calendar quarter such that the closing date of the first set and the shipment date of the second are at least 15 days apart; and

4. Have its accreditation reinstated upon receipt of Acceptable Results for both PT studies, or have its accreditation for that UoA revoked if either or both sets of PT study results are Not Acceptable.

(c) Each laboratory shall conduct PT studies as follows:

(1) Under the same conditions as those under which the routine analysis of environmental regulatory compliance samples are conducted in terms of methods used, laboratory staff members involved, handling, and processing;

(2) Except for UoAs in FoAs 122, 123, and 124, using PT samples that:

(A) Meet the design, execution, and reporting requirements in the NELAC Standards; and

(B) Have been obtained from a provider designated by ELAP, based on a demonstration that the provider meets the requirements contained in the NELAC Standards, and/or has been accredited by a NELAC-designated Proficiency Testing Oversight Body/Proficiency Testing Provider Accreditor (PTOB/PTPA), such as NIST/NVLAP or the American Association for Laboratory Accreditation (A2LA); and

(3) For toxicity bioassay PT studies for any FoA, using PT samples prepared and scored pursuant to the "National Standards for Water Proficiency Testing Studies, Criteria Document, Toxicity Studies", Part 3, January 31, 2001.

(4) For UoAs in FoAs 122, 123, and 124, using PT samples approved by ELAP in conjunction with the California Department of Food and Agriculture.

(5) For UoAs in FoAs 101 and 108, using PT samples approved by ELAP in conjunction with the Federal Food and Drug Administration.

(e) A laboratory conducting PT studies for UoAs in FoAs 115 through 121, may meet the PT study requirements as follows:

(1) For aqueous liquids, by analyzing a liquid PT sample; and/or

(2) For solids and/or non-aqueous liquids, by analyzing a solid phase PT sample.

(e) A laboratory conducting PT studies for UoAs in FoAs 122, 123, and 124 shall complete all PT studies provided by ELAP up to four studies, if available, within twelve months from the date of receipt by the laboratory and achieve Acceptable Results in a minimum of two.

(f) For a California analyte for which there is no PT study available that meets the requirements in Subsection (c)(2)(A and B), a laboratory shall conduct a PT study that has been provided to it by ELAP along with the acceptance criteria and concentration ranges for the study. The criteria and ranges will have been based on the Environmental Laboratory Technical Advisory Committee recommendations.

(g) If a laboratory has a financial interest, familial relationship, or contractual agreement for consultation with the provider of a PT study, the results from that study shall not be used to meet the PT study requirements for accreditation.

§64809. On-Site Assessment.

(a) Each laboratory shall be subject to an on-site assessment to obtain its initial certificate and every two years thereafter by ELAP to verify the information submitted with its ELAP certificate application pursuant to Section 64803(a), including compliance with requirements in:

(1) Methods used for each UoA for which the laboratory seeks accreditation;

(2) Section 64812 (Laboratory and Equipment);

(3) Section 64813 (Quality Assurance); and

(4) Section 64814 (Personnel)

(b) Within 30 days of the on-site assessment, the laboratory will receive a notice of deficiencies related to compliance with Subsection(a) from ELAP.

(1) Within 30 days of receipt of the deficiencies notice from ELAP, the laboratory shall submit a corrective action report to ELAP that details how each identified deficiency has been investigated and corrections initiated and/or completed; the laboratory will be notified within 30 days whether the corrective action report demonstrates the corrections;

(2) If the laboratory is notified by ELAP that the corrective action report does not adequately address the identified deficiencies, the laboratory shall have an additional 30 days from its receipt of the notification to submit a revised corrective action report; if the revised report still does not demonstrate the required corrections, accreditation shall be denied or revoked for any UoAs affected by failure to take corrective action

(3) Prior to the deadline for report submission, a laboratory may request in writing that ELAP allow additional time to complete the report. The laboratory will be notified within 10 days of ELAP's receipt of such a request whether the extension has been approved, based on an evaluation of the reasons provided by the laboratory.

§64810. Reciprocity Agreement.

(a) Another State or federal agency's environmental laboratory accreditation program shall be recognized for the purposes of reciprocity if the program's requirements related to proficiency testing, on-site assessments, quality assurance, laboratory facilities and equipment, test methods, and personnel are at least as stringent as the ELAP accreditation requirements in this chapter.

(b) Where reciprocity exists, each laboratory seeking accreditation shall submit:

(1) An application pursuant to Section 64804(a);

(2) Copies of the PT study results from the most recent study conducted by the laboratory for the other program;

(3) Copies of the most recent on-site assessment report prepared by the other program and the laboratory's response to any deficiencies noted;

(4) Fees pursuant to Section 64805; and

(5) A copy of the certificate, license, permit, or authorization to operate as an environmental laboratory issued to the laboratory by the other program.

(c) When a reciprocity agreement exists between the Department and another state, only those laboratories that reside within the boundaries of the other State shall be eligible for accreditation through reciprocity.

(d) If a laboratory that is accredited through reciprocity has its certificate suspended or revoked by the other State or federal agency's environmental laboratory accreditation program, it shall notify ELAP within 10 days of the suspension or revocation and its ELAP certificate shall be suspended or revoked as of the effective date of the action taken by the other program.

(e) If a reciprocity agreement with another state or federal agency is revoked, any certificate issued by ELAP to an affected laboratories shall be valid until the certificate expiration date.

(f) When ELAP conducts a site assessment for an out-of-state laboratory accredited, the laboratory shall reimburse ELAP for all per diem and travel expenses incurred.

§64811. Change of Laboratory Ownership.

(a) To apply to operate under the laboratory's existing ELAP certificate until its expiration date and to temporarily operate while the application is being processed, within thirty days of the effective date of the laboratory ownership change, the new owner shall submit a written request to ELAP to retain the certificate, be subject to an on-site assessment, pursuant to Section 64808, and provide the following in writing to ELAP, as a minimum:

(1) Name(s) of the new owner(s);

(2) Effective date of the change of ownership;

(3) Names of all Analytical Specialists who quit, or were terminated and replaced as of the effective date of the ownership change; and the names of all Analytical Specialists hired as replacements.

(4) Qualifications of personnel, addressing the requirements in Section 64814 for laboratory director and analytical specialist;

(5) Statement that the new owner will operate pursuant to the laboratory's existing certificate and will not change any of the following without requesting and obtaining written approval from ELAP:

(A) laboratory location,

(B) equipment

(C) methodology

(D) quality assurance practices

(6) Statement that the new owner will retain all records and data of analyses performed by the previous owner for a minimum of five (5) years.

(7) Signature of one or more of the new owner(s), or their agents.

(b) The laboratory under new ownership shall have its certificate revoked as of the effective date of the ownership change if:

(1) It does not comply with the requirements in Subsection (a);

(2) If the new owner relocates the laboratory without ELAP approval; or

(3) If more than half the laboratory's technical staff either quit or are terminated and replaced by the new owner upon assuming ownership.

(c) The laboratory under new ownership shall be subject to having its certificate revoked upon ELAP notification if an on-site assessment indicates inconsistencies with the information provided pursuant to Subsection (a);

§68412. Laboratory and Equipment.

(a) A laboratory shall be arranged and operated so that:

(1) Utilities, ventilation, and environmental control are designed and maintained to allow the laboratory equipment to function and produce analyses for each UoA and FoA for which the laboratory is accredited;

(2) The design, arrangement, and operation of the laboratory minimizes the potential for sample contamination;

(3) The storage and handling of hazardous materials is in accordance with the California Code of Regulations, Title 8, General Industry Safety Orders; and

(4) The disposal of chemical wastes is in accordance with the California Code of Regulations, Title 22, Division 4.5, Environmental Health Standards for the Management of Hazardous Wastes.

(b) Each piece of laboratory equipment shall meet all operational, quality assurance, quality control, and design criteria established in the method(s) employed by the laboratory.

(c) Each piece of laboratory equipment shall be operated and maintained by the laboratory pursuant to the equipment manufacturer's maintenance instructions.

(d) Records shall be retained of all operational and maintenance activities associated with the operation of laboratory equipment.

§64813. Quality Assurance.

(a) To obtain and maintain ELAP accreditation, each laboratory shall

(1) Implement a quality assurance and quality control program, as described in its quality assurance manual; and

(2) Demonstrate during onsite assessments that it is operating in conformance with its quality assurance manual and following the procedures specified in the test methods for which it is accredited.

(b) Each laboratory shall develop a quality assurance manual, submit a copy to ELAP for approval, and annually review and update the manual; the manual shall include the following:

(1) A quality policy statement, including objectives and commitments, by top management;

(2) Organization and management structure of the laboratory, its place in any parent organization and relevant organizational charts, and the name of the person responsible for the implementation of the quality assurance manual;

(3) Relationship between management, technical operations, support services and the quality system;

(4) Procedures to ensure that all records required under this Chapter are retained, as well as procedures for control and maintenance of documentation through a document control system that ensures that all standard operating procedures, manuals, or documents clearly indicate the time period during which the procedure or document was in force;

(5) Job descriptions of key staff and reference to the job descriptions of other staff;

(6) Identification of the laboratory's approved signatories; at a minimum, the title page of the Quality Manual must have the signed and dated concurrence of all responsible parties including the agent who is in charge of all laboratory activities, along with their titles;

(7) The laboratory's procedures for achieving trace-ability of measurements;

(8) A list of all test methods under which the laboratory performs its accredited testing;

(9) Mechanisms for ensuring that the laboratory reviews all new work to ensure that it has the appropriate facilities and resources before commencing such work;

(10) Reference to the calibration and/or verification test procedures used, including reference to the use of analytical reagent grade and purity as specified in the methods;

(11) Procedures for handling submitted samples;

(12) Reference to the major equipment and reference measurement standards used as well as the facilities and services used by the laboratory in conducting tests;

(13) Reference to procedures for calibration, verification and maintenance of equipment;

(14) Reference to verification practices which may include interlaboratory comparisons, proficiency testing programs, use of reference materials and internal quality control schemes;

(15) Procedures to be followed for feedback and corrective action whenever testing discrepancies are detected, or departures from documented policies and procedures occur;

(16) The laboratory management arrangements for permitting departures from documented policies and procedures or from standard specifications;

(17) Procedures for dealing with complaints;

(18) Procedures for protecting confidentiality (including national security concerns), and proprietary rights;

(19) Procedures for audits and data review;

(20) Processes/procedures for establishing that personnel are adequately experienced in the duties they are expected to carry out and receive any needed training;

(21) Data integrity procedures signed and dated by senior laboratory management that include, as a minimum: Data integrity training; signed data integrity documentation for all employees; in-depth, periodic monitoring of data integrity; and data integrity procedure documentation;

(22) Reference to procedures for reporting analytical results;

(23) Up-to-date instructions, standards, manuals and reference data on the use and operation of all analytical and auxiliary equipment;

(24) Standard operating procedures that reflect all phases of laboratory activities, including assessment of data integrity, corrective actions, handling consumer complaints and all test methods;

(25) Laboratory standard operating procedures for each combination of accredited test method and analyte;

(26) Laboratory documentation of annual quality control report, and management review;

(27) Laboratory subcontracting procedures that include ways to insure that a subcontractor conforms to the applicable statutory and regulatory requirements for performing tests and submitting test results; and

(28) A table of contents, and applicable lists of references and glossaries, and appendices.

(c) Each laboratory accredited for drinking water compliance testing shall demonstrate compliance with the requirements in the *Manual for the Certification of Laboratories Analyzing Drinking Water (EPA 815-B-97-001) (Chapter IV-Chemistry; Chapter V Microbiology; Chapter VI-Radiochemistry).* If a regulation has established more stringent requirements for a test method, the laboratory shall demonstrate compliance with those requirements.

(d) Prior to accepting and instituting a test method, and at any time that there is a change in the type of instrument, personnel or method, the laboratory shall submit a demonstration of technical capability to ELAP.

(e) Each laboratory shall maintain up-to-date records for every technical staffperson and contracted personnel documenting that each:

(1) Reads annually, understands, and uses the laboratory's most current quality assurance procedures that pertain to his/her responsibilities;

(2) Has been trained at least annually in the procedures; and

(3) Has been annually reviewed for a demonstration of capability.

(f) If an analytical method does not have quality control procedures, a laboratory shall use the following:

(1) For UoAs in FoAs 101 through 114, *Standard Methods for the Examination of Water and Wastewater*, Section 1020 B, pp 1-5 through 1-11, 20th edition (1998), or Standard Methods Online (www.standardmethods.org), April 2004;

(2) For UoAs in FoAs 115 through 121, *Test Methods for Evaluating Solid Waste, Physical/Chemical Methods,* (SW-846) U.S.E.P.A., third edition; and

(3) For FoAs 122 through 124, the quality control procedures specified by the Department of Food and Agriculture, on the basis of the intended use of the analytical data.

§64814. Laboratory Personnel.

(a) Each laboratory shall designate a laboratory director. Except as provided in Subsection (d), the laboratory director shall have as a minimum:

(1) A baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science.

(2) Three years experience in the analysis of water, wastewater, solid waste, hazardous waste or other environmental samples, prior to being designated laboratory director, subject to the following allowances:

(A) A master's degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science may be substituted for one year of the required experience.

(B) A doctorate in chemistry, biochemistry, environmental, sanitary or chemical engineering, biology, microbiology, natural or physical science may be substituted for two years of the required experience.

(b) Except as provided in Subsection (d), prior to being designated an analytical specialist, a person shall have as a minimum a baccalaureate degree in chemistry, biochemistry, biology, microbiology, environmental, sanitary or chemical engineering, natural or physical science; and, if working for the laboratory, be under the supervision of a laboratory director or analytical specialist; and have:

(1) A certification of completion for a course taught by the manufacturer of the sophisticated laboratory instrument which is being used or supervised by the analytical specialist; or

(2) Six months experience operating a sophisticated laboratory instrument to analyze water, wastewater, solid waste, hazardous waste or other environmental samples, or food.

(c) As a minimum, the laboratory director and analytical specialist(s) employed by a laboratory owned by a public drinking water or wastewater utility shall have Analyst/Water Quality Analyst Certificates from the California Water Environment Association (CWEA) or the California-Nevada Section of the American Water Works Association (CA-NV/AWWA), pursuant to Table 64814, as follows:

(1) A laboratory director shall have the highest certificate grade required for the performance of any FoA for which the laboratory is accredited.

(2) An analytical specialist shall have the certificate grade required for the FoA(s) that the analytical specialist performs for the laboratory.

Table 64814
Personnel Certification

Fields of Accreditation (FoAs)	***Minimum Certificate Grade***
101, 102*, 107, 108**	I
102, 108, 112; those allowed for a grade I	II
103***, 104***, 105, 109***,110***, 111; those allowed for a grade II	III
103, 104, 106, 109, 110, 113; those allowed for a grade III	IV
* Limited to testing for alkalinity, chloride, hardness, total filterable residue, and conductivity. ** Limited to testing for acidity, alkalinity, biochemical oxygen demand, chemical oxygen demand, chlorine residual, hardness, dissolved oxygen, pH, total residue, filterable residue, non-filterable residue, settleable residue, volatile residue, specific conductance, and turbidity. ***Limited to testing for non-Mass Spectroscopy techniques.	

(d) A laboratory director or analytical specialist that was employed by a laboratory at the time that it was accredited prior to, or as of, December 31, 1994, shall be exempt from meeting Subsections (a), (b) and (c).

(e) A laboratory director, or his/her designee, shall be responsible for:
(1) All analytical and operational activities of the laboratory; and
(2) The accuracy and quality of all data reported by the laboratory.

(f) A laboratory director shall assume the position of, or shall designate another person as, the analytical specialist responsible for the use of each sophisticated laboratory instrument in the laboratory.

(g) If a laboratory director leaves and is not replaced within 15 days by a person meeting the laboratory director requirements in this section, a person or persons with lesser qualifications may serve as a temporary director for a period not to exceed ninety days, provided that the laboratory notifies ELAP, describing the qualifications of the temporary director and receives written approval from ELAP. An additional extension of no more than ninety days beyond the original 90-day period may be granted by ELAP, provided the laboratory can document that its good-faith efforts to recruit a qualified director were unsuccessful for reasons beyond its control.

§64815. Notification, Reporting, and Records Retention.

(a) Laboratories certified for FoAs 101, 102, 103, 104, 105 and/or 106 shall conform to the following reporting and notification requirements.

(1) Laboratories reporting bacterial quality results as required by Title 22, California Code of Regulations, Section 64423.1 shall submit a bacterial monitoring report including information required in Title 22, California Code of Regulations, Sections 64423.1(c)(2) and (c)(3) directly to the Department.

(2) The laboratory shall notify a water supplier's designated contact person as soon as possible, but within 24 hours, and record the method and time of notification or attempted notification, whenever any of the following occur:

(A) The presence of total coliforms, fecal coliforms, or Escherichia coli (E. coli) is confirmed.

(B) A bacterial sample is invalidated due to an interference as defined in Title 22, California Code of Regulations, Section 64425(b).

(C) A nitrate sample exceeds the MCL.

(3) If the laboratory is unable to make direct contact with the supplier's designated contact person within 24 hours, pursuant to subparagraphs (2)(A) or (C), the laboratory shall immediately notify the Department and provide a written record of the time and method of attempted contacts.

(4) All analytical results conducted pursuant to Title 22, California Code of Regulations, Chapter 15, Domestic Water Quality and Monitoring, shall be reported directly to the Department electronically using the Electronic Deliverable Format as defined in The Electronic Deliverable Format [EDF] Version 1.2i Guidelines & Restrictions dated April 2001 and Data Dictionary dated April 2001, by the 10th day of the month following the month in which the analyses were completed.

(5) Whenever a laboratory is requested by a water supplier, pursuant to Title 22, California Code of Regulations, Section 64425(a)(2), to submit evidence invalidating a sample due to laboratory error, the laboratory shall provide the supplier with information which shall include:

(A) A letter from the Laboratory Director to the water supplier agreeing to the invalidation request by reason of laboratory accident or error;

(B) Complete sample identification, laboratory sample log number (if used), date and time of collection, date and time of receipt by the laboratory, date and time of analysis for the sample(s) in question;

(C) Complete description of the error alleged to have invalidated the result(s);

(D) Copies of all analytical, operating, and quality assurance records pertaining to the incident in question; and

(E) Any observations noted by laboratory personnel when receiving and analyzing the sample(s) in question.

(b) Laboratories certified for FoAs 122 and 123 shall verify the identity and quantity of a pesticide residue before reporting the results.

(c) In any arrangements between laboratories involving the transfer of samples, or portions of samples, the laboratory issuing the report of analyses shall include the original of any report(s) (or copy of the original) prepared by all other laboratories who are party to the agreement.

(d) Each laboratory shall maintain comprehensive records of all laboratory activities, including original observations, calculations and derived data, calibration records and copies of test reports for a minimum of five (5) years

NOTE: Authority cited: Sections 100275, 100830, 100835 and 116375, Health and Safety Code. Reference: Sections 100825(b) and 100835, Health and Safety Code.